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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,520	06/27/2003	Matthias Gerlach	103832-506-NP	8727

24964 7590 04/21/2008

GOODWIN PROCTER L.L.P
ATTN: PATENT ADMINISTRATOR
599 LEXINGTON AVE.
NEW YORK, NY 10022

EXAMINER	
WARD, PAUL V	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
04/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/608,520	GERLACH ET AL.	
	Examiner	Art Unit	
	PAUL V. WARD	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,15,16 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 15-16 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments Regarding

Claim Objection and Rejections - 35 USC § 102 & 112

1. The objection and rejections, under 35 USC *§ 102,* of claims 1-11, 15-16 and 20, have been overcome by Applicant's amendment in the reply filed November 19, 2007.

2. The rejections of claims 1-11, under 35 USC § 112, for reciting "solvates", "tolerable", "claims 1", the phrase "such as", for using quotation marks, and for not ending the claim with a period, have been overcome by Applicant's amendment in the reply filed November 19, 2007.

Response to Arguments Regarding

Claim Objection and Rejections - 35 USC § 112, first paragraph

3. Applicant's arguments, regarding claim 14, filed November 19, 2007 have been fully considered but they are not persuasive. Applicant contends that as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement is satisfied. However, applicant's argument is misplaced.

35 U.S.C. 112 provides that:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Here, claim 14 fails to comply with the enablement requirement under 35 U.S.C. 112, first paragraph since the claim contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with

which it is most nearly connected, to make and/or use the invention without undue experimentation.

The claim is directed to a pharmaceutical composition or compositions comprising the claimed compounds. The claims are rejected for lack of enablement because there is an insufficient teaching of how to use the claimed compositions as claimed. The term "pharmaceutical composition" specifies that at least some therapeutic benefit arise from some property of the composition. However, Applicant has not taught how to use the compounds of the invention to therapeutic effect for any condition.

Additionally, claim 4 is directed to a composition for use in the treatment of tumors. The term "tumors" is interpreted to include any and all forms of tumors/cancers. In light of this, it can be asserted that in spite of the vast expenditure of human and capital resources in recent years, no one drug has been found which is effective in treating all types of tumors/cancers because it is not a simple disease, nor is it even a single disease, but a complex of a multitude of different entities, each behaving in a different way. In re Hozumi, 226 USPQ 353 (ComrPats 1985).

The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the

enablement requirement and whether any necessary experimentation is "undue".

These factors include, but are not limited to:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

The breadth of the instant claims is seen to encompass methods for treating tumors/cancers by administering to a patient in need of such treatment a therapeutically effective amount of the compound claim. Applicant failed to exactly defined what types of tumors/cancers are treated. Thus, claim 14 is extremely broad.

The nature of the invention

The nature of the invention is the treatment of tumors/cancers through the use of the claimed compound and derivatives thereof. Currently, there are no known agents that treat cancers all inclusively.

The level of predictability in the art

The treatment of tumors/cancers is highly unpredictable due to the differing forms of cells, their location, their potential for metastases. The fact that tumors/cancers

therapeutics is palliative rather than curative and that tumor/cancer treatment readily harms normal tissues.

The amount of direction provided by the inventor.

The applicant has not demonstrated sufficient guidance provided in the form of administration profiles, combination ratios of the active agents or reference to the same in the prior art to provide a skilled artisan with sufficient guidance to practice the instant treatment of tumor/cancer claimed. Further, the applicant discloses that an effective amount of the compound will be administered without providing any direction other than that the compounds of the invention have a high therapeutic index and follows this with a definition readily found in a basic pharmacology textbook. It should be noted that the therapeutic index of a drug in humans is almost never known and is only determined through clinical experience.

The existence of working examples.

There is not seen in the disclosure, sufficient evidence to support Applicant's claims of treating tumor/cancer. A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 27 USPQ2d 1510 (CAFC). The disclosure does not demonstrate sufficient evidence to support the applicant's claim to the treatment of tumor/cancer. There are not sufficient representations or data from references of the prior art to provide a nexus between those examples and a method of treating tumor/cancer with the claimed compound.

The level of one of ordinary skill.

The level of skill is that of one with a doctoral understanding of tumor/cancer therapeutics.

The quantity of experimentation.

A great deal of experimentation is required. In order for there to be a method of treating tumor/cancer generally, as claimed by the applicant, it would be necessary to show that a vast range of different types of tumors/cancers can be treated that have differing cell types, locations and potentials for metastases. Furthermore, direction, in the form of examples, must be shown to determine what an effective dose may be. The references submitted do not demonstrate this. Therefore, one of ordinary skill in the art would require a significant amount of experimentation in order to determine the effective dosage to treat the multitudes of different types of tumor/cancer with the claimed compound individually or in combination with other therapeutic agents. Thus, it can be safely concluded that the instant case fails to provide an enabling disclosure for the treatment of tumor/cancer.

Therefore, the rejection of the claim under 35 U.S.C. 112, first paragraph is maintained for the reasons of record as set forth today and in the Office Action dated June 18, 2007.

Response to Arguments Regarding

Claim Objection and Rejections - 35 USC § 103

4. Applicant's arguments, regarding claims 1-11, 15-16 and 20, filed November 19, 2007, have been fully considered but they are not persuasive.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-11, 15-16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu et al. (WO 01/19798).

Applicant argues that the finding of obviousness is improper because the amended claims are a subgenus, and the fact that a claimed subgenus is encompassed by a prior art genus is not sufficient by itself to establish obviousness. Applicant's argument is misplaced.

Zhu describes very similar subject matter to that claimed herein directed to amended claim 1, its compositions and uses. See formula 1, page 11. Note on p. 39 the compounds appearing in Table 8. The analogs differ from claim 1 in being substituted

by naphthalene vs. instant phenyl or anthracene. See formula 1, page 11 and definitions for A, Q, D, E, G, J and X. The claims differ from the reference by reciting specific species and a more limited genus than the reference. Thus it would have been obvious to one skilled in the art at the time the instant invention was made to modify the prior art compounds as discussed above in Zhu and in so doing obtain additional compounds for uses. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. A prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus.

Thus, instant claimed invention would have been obvious to one of ordinary skill in the art. Therefore, the rejection of the claims, under 35 USC § 103, is maintained for the reasons of record as set forth today and in the Office Action dated June 18, 2007.

New Matter

The amendment filed November 19, 2007 s objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows (were underlined):

> R_4: unsubstituted or substituted aryl, unsubstituted or substituted heteroaryl, unsubstituted or substituted alkylaryl, unsubstituted or substituted alkylhetaryl, wherein the heteroaryl radical can be pyrolyl, furyl, thienyl, thiazolyl, triazolyl, tetrazolyl, oxazolyl, isothiazolyl, isoxazolyl, pyrazolyl, imidazolyl, pyridinyl, pyrimidinyl, pyrazinyl, triazinyl, benzothiazolyl, indolyl,

indolizinyl, quinolinyl, isoquinolinyl, cinnolinyl, quinoxalinyl, phthalazinyl, carbazolyl, phenazinyl, phenothiazinyl, purinyl, acridinyl, phenanthrinyl;

Applicant is required to cancel the new matter in the reply to this Office Action.

Conclusion

Claims 1-11, 15-16 and 20 are pending. Claims 1-11, 15-16 and 20 are rejected. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL V WARD whose telephone number is 571-272-2909. The examiner can normally be reached on M-F 8 am to 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/608,520	GERLACH ET AL.	
	Examiner	Art Unit	
	PAUL V. WARD	1624	